

**REMARKS**

Claims 74-121 were pending in the application. Claims 83, 84, 88, 90, 91, 93, 95, 97, 103, 105, 106, 108, and 110-112 have been amended. New claims 122-142 have been added. Accordingly, claims 74-142 are currently pending in the application. Support for the new claims can be found in the claims as originally filed and throughout the specification, including at least at page 29, line 28 to page 32, line 35. No new matter has been added. The foregoing claim amendments and cancellations should in no way be construed as an acquiescence to any of the Examiner's rejections, and have been made solely to expedite the prosecution of the application. Applicant reserves the right to pursue the claims as originally filed in this or a separate application(s).

Rejection of Claims 83-84, 88-98, 103, and 105 Under 35 U.S.C § 112, second paragraph

The Examiner has rejected claims 83-84, 88-98, 103, and 105 under 35 U.S.C. 112, second paragraph "as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention."

The Examiner has rejected claim 83 as being improper for "containing a twice recited member." Applicant has amended claim 83 to delete one reference to the "intravenous immune globulin," thus rendering the rejection moot.

The Examiner has rejected claim 83 for use of the phrases "orally administered peptides" and "thalidomide related drugs." The Examiner states that these phrases are "unclear because these have no structural or functional limitations." Applicant traverses the rejection of claim 83 for use of the phrases "orally administered peptides" and "thalidomide related drugs," however in the interest of expediting prosecution Applicant has deleted each phrase from claim 83. In view of the amendments to claim 83, Applicant submits that the rejection of claim 83 relating to use of the phrases "orally administered peptides" and "thalidomide related drugs" is rendered moot.

The Examiner has rejected claim 83 for use of the phrases "such as" and "including" which the Examiner alleges are indefinite. Applicant has amended claim 83 to delete use of the phrase "such as" and "including" thus rendering the rejection moot.

The Examiner has rejected claim 84 for being incomplete. Applicant has amended claim 84 accordingly, thus rendering the rejection moot.

In addition, Applicant has amended claims 88, 90, 96, 103, 105, and 111 to the extent that the rejections relating to claim 83 apply.

In view of the amendments to claims 83-84, 88-98, 103, and 105, Applicant respectfully requests that the rejection of the claims under 35 U.S.C. 112, second paragraph be withdrawn.

Rejection of Claims 83, 88, 90, 103, and 105 Under 35 U.S.C § 112, first paragraph

The Examiner has rejected claims 83, 88, 90, 103, and 105 under 35 U.S.C., first paragraph for allegedly containing new subject matter.

The Examiner has rejected claims 83, 88, 90, 103, and 105 for use of the phrase “collagen,” and states that the specification teaches “orally administered collagen.” Applicant respectfully traverses this rejection on the basis that the specification teaches oral administration of collagen as an example of a mode by which collagen can be administered (see page 31, line 3 of the instant specification). In the interest of expediting prosecution, however, Applicant has amended the claims to refer to “orally administered collagen,” thus rendering the rejection moot.

The Examiner has rejected claims 88 and 103 as containing new matter “because they are not limited to treatment of a particular disease.” Applicant respectfully traverses this rejection. In the specification, Applicant teaches use of antibodies of the invention for the treatment of a disorder in which TNF $\alpha$  activity is detrimental. Applicant provides numerous examples of such disorders in the specification, including at page 36, line 5 to page 40, line 17. Applicant also teaches that the antibodies of the invention can be administered in combination with certain additional therapeutic agents for the treatment of disorder in which TNF $\alpha$  activity is detrimental. For example, at page 29, lines 14 to 24 and at page 33, lines 1-2 of the instant specification, Applicant teaches that “an anti-hTNF $\alpha$  antibody or antibody portion of the invention may be coformulated with and/or coadministered with one or more additional therapeutic agents which are useful for treating disorders in which TNF $\alpha$  activity is detrimental.” Applicant submits that additional therapeutic agents described for certain disorders in the specification, *e.g.*, rheumatoid arthritis, are not limited to a specific disorder and are provided as examples of additional therapeutic agents useful for treating disorders in which TNF $\alpha$  activity is detrimental. Thus, Applicant submits that claims 88 and 103 do not contain new matter relative to the original disclosure, and, furthermore, that the specification fully enables one of ordinary skill in the art to make and use the claimed invention.

The Examiner has also rejected claims 88, 89, 90, 103, and 105 under 35 U.S.C., first paragraph for use of the phrase “orally administered peptides.” Applicants have amended the claims to delete reference to this phrase, thus rendering the rejection moot.

In view of the above-mentioned amendments and arguments, Applicant respectfully requests that the rejection of claims 83, 88, 90, 103, and 105 under 35 U.S.C., first paragraph be reconsidered and withdrawn.

#### Rejection of Claims 101 and 120

Applicant has amended claims 101 and 120 to correct claim informalities, thus rendering the rejection moot.

#### Rejection of Claims Under 35 U.S.C § 101

Claims 74-82 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8, 24-25, and 28 of U.S. Patent No. 6,090,382. Claims 74 and 83 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 24-25 of U.S. Patent No. 6,090,382 in view of Aggarwal (U.S. Patent No. 5,795,967). Claims 84-87, 89, 91, 93, 95, 97, 99-102, 104, 106, 108, 110, and 112 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 4-7, 15, 17, 22, 36-39, 69, 87, and 93 of U.S. Patent No. 6,509,015. Claims 84-91, 93-97, 99-106 and 108-112 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 4-7, 15, 17, 22, 36-39, 69, 87, and 93 of U.S. Patent No. 6,509,015 in view of Aggarwal (U.S. Patent No. 5,795,967). Claims 84-87, 92, 98-102, 107, and 113 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 4-7, 36-39, and 69 of U.S. Patent No. 6,509,015. Claims 114-121 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 4-7 and 36-39 of U.S. Patent No. 6,509,015.

While in no way admitting that the above-mentioned claims are obvious over the cited claims of U.S. Patents 6,090,382 and 6,509,015, upon allowance of the instant application, Applicant will consider submitting a terminal disclaimer upon indication that the claims are allowable.

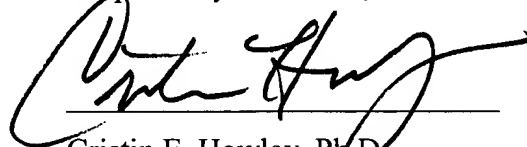
Moreover, Applicant objects to the double patenting rejections made in view of Aggarwal as being improper. The judicially created doctrine of obviousness-type double patenting “requires rejection of an application claim when the claimed subject matter is not patentably distinct from the subject matter *claimed* in a commonly owned patent.” (see MPEP 804). Applicant submits that the Aggarwal patent does not *claim* the instant invention, and, therefore, is not available for use in a rejection relating to the judicially created doctrine of obviousness-type double patenting. Applicant respectfully requests reconsideration and withdrawal of the obviousness-type double patenting rejection in view of Aggarwal.

#### SUMMARY

In view of the foregoing remarks, reconsideration of the rejections and allowance of all pending claims is respectfully requested. It is respectfully submitted that any amendments and/or cancellations of the claims should in no way be construed as an acquiescence to the Examiner’s rejections and/or objections.

If a telephone conversation with Applicant’s Attorney would expedite the prosecution of the above-identified application, the Examiner is urged to call Applicant’s Attorney at (617) 227-7400.

Respectfully submitted,



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In re Application of: Jochen G. Salfeld *et al.*

Application No. 09/801185

Filed: March 7, 2001

Title: HUMAN ANTIBODIES THAT BIND HUMAN TNF $\alpha$

Attorney Docket No. BBI-043CPUSCNRCE

Art Unit: 1644

The practitioner named below is authorized to conduct interviews and has the authority to bind the principal concerned. Furthermore, the practitioner is authorized to file correspondence in the above-identified application pursuant to 37 CFR 1.34:

Name Registration Number

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**This is not a Power of Attorney to the above-named practitioner.** Accordingly, the practitioner named above does **not** have authority to sign a request to change the correspondence address, a request for an express abandonment, a disclaimer, a power of attorney, or other document requiring the signature of the applicant, assignee of the entire interest or an attorney of record. If appropriate, a separate Power of Attorney to the above-named practitioner should be executed and filed in the United States Patent and Trademark Office.

SIGNATURE of Practitioner of Record

Name Giulio A. DeConti, Jr.

Signature

Date June 28, 2004

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## **AUTHORIZATION TO ACT IN A REPRESENTATIVE CAPACITY**